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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/789,422 | 02/27/2004 | Boris Y. Shekunov | FER-14668.001 | 5255 |
| 7609 | 7590 | 06/15/2006 | EXAMINER | |
| RANKIN, HILL, PORTER & CLARK, LLP | | | DRODGE, JOSEPH W | |
| 925 EUCLID AVENUE, SUITE 700 | | | ART UNIT | |
| CLEVELAND, OH 44115-1405 | | | PAPER NUMBER | |

1723

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,422

Applicant(s)

SHEKUNOV ET AL.

Examiner

Joseph W. Drodge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Claims 15-31 are objected to because of the following informalities: The instant application has omitted claims 13 and 14, hence claims 15-31 are misnumbered, and should be renumbered as claims 13-29 in a subsequent Amendment. Appropriate correction is required.

For convenience, however, the claims will be referred to by their original numbering in the balance of this Office Action.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of Patent 6,998,051. The instant method claims, although differently worded and organized substantially differ only in omitting the method step of maintaining the supercritical fluid as a supercritical phase until the precipitating of particles occurs. However, it would have been obvious to one of ordinary skill in the art to have modified the method of the '051 claims to include such maintaining since the language of the instant claims "contacting the

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solution with the supercritical fluid to extract ...and precipitate the solute" suggests that the supercritical fluid is in a supercritical state when the extraction and precipitation occurs.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Sievers et al patent 5,639,441. Sievers et al disclose producing of particles [as in claims 10 and 15] comprising providing supercritical fluid, 1st solvent soluble in such fluid, 2nd insoluble solvent, the 2nd solvent optionally being partially soluble in the 1st solvent, and solute, contacting these together to form a solution, then contacting the solution with supercritical fluid to extract 1st solvent from the solution and precipitate the solute in the form of particles suspended in the 2nd solvent (all disclosed at column 5, line 66-column 6, line 61, column 6, line 66-column 7, line 5 indicate that the solution of solvents and solute are formed before contacting with supercritical fluid).

The solute contains a biologically active substance as in claims 2 and 11 (column 5, lines 22-36). The supercritical fluid is carbon dioxide as in claim 3 (column 6, line 44). There may be plural solutes as in claim 4 (column 5, lines 36-40). There is also a 2nd solute comprising a polymer, wax or lip as in claims 5 and 12 (column 5, line 37).

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The 1st solvent may be an alcohol or acetone organic solvent as in claims 6, 13 and 7 (column 5, lines 66-67 and column 6, line 51) while the 2nd solvent is water (column 6, lines 57-59) as in claim 8. The particle size is from 10 nm to 10 microns (column 6, lines 33-36) for claims 9 and 14.

For claim 16, Sievers also disclose apparatus features of extraction vessel 20, means for removing formed particles 22, 34, 24, 1st supercritical fluid reservoir source 10, 1st pump 12, 2nd solution reservoir source 14, 2nd pump 16, and a restrictor, backpressure maintaining means for removing the mixture at column 11, line 66-column 12, line 5. Sievers infers that flow control restrictors are interchangeable, or combinable, with flow control release valves, as instantly claimed, at column 10, lines 55-56.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Andersson et al patent 6,372,260 is of interest for forming particles by forming an emulsion and contacting with supercritical fluid.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached at 571-272-1151. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

June 12, 2006


JOSEPH DRODGE
PRIMARY EXAMINER